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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/763,791 | 04/25/2001 | David Russell Blake | 9374.21USWO | 3690 |

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| EXAMINER |
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WEBER, JON P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1651 | |

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|------------------------|---------------------|
| | 09/763,791 | BLAKE ET AL. |
| Examiner | Art Unit | |
| Jon P Weber, Ph.D. | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 April 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-18,35,38 and 39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-18,35,38 and 39 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) ✓
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19.
4) Interview Summary (PTO-413) Paper No(s). ____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, response with amendment and IDS, filed on 08 April 2003 has been entered.

Claims 1-18, 35 and 38-39 are now presented for examination.

It is noted that claim 35 depends from canceled claim 33 and has been treated as if it depended from claim 16.

Claim Rejections - 35 USC § 102

Claims 1, 7-8, 11 and 15 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cooray et al. (1995).

Claims 1-4, 6-11 and 14-17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al. (1976).

Claims 1-17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ho et al. (1978).

Claims 1 and 6-10 stand rejected under 35 U.S.C. 102(b) as being anticipated by De Jong et al. (US 5,747,078).

It is still argued that cow's milk *per se* is not suitable for human infant formula feed as a breast milk substitute. Two references are provided to allegedly support this position.

The references cited provide the following teachings. Cow's milk is not the best substitute for human milk because 1) it does not provide the same balance of nutrients, and 2) it may be allergenic to infants under one year. First, neither the references nor the disclosure provide a definition for an infant. The dictionary provides little further guidance, only indicating that an infant is in the earliest stage of life. The legal definition states that an infant is in the age of minority (less than 18). Thus, there is no reason to suppose that an infant formula is limited to infants aged less than one year. Infants over one year would not be contraindicated at all for cow's milk formula by these references. Second, these statements are only guidelines, they do not state that one cannot use cow's milk based formula feeds. As evidenced by two textbooks on nutrition, Twombly (1984) and Blogert et al. (1973), cow's milk based formula feeds have been known for hundreds of years. Cow's milk must be diluted to reduce the protein and calcium concentration and fortified by addition of sugar, vitamins and minerals to make a properly balanced formula. However, the claims recite "comprising" and allow for the addition of other ingredients, especially ones known in the art to be added to such compositions. There is no doubt that all of these references indicate that breast milk is preferred over formula feeds. Nevertheless, a formula feed suitable for human infants can comprise cow's milk. In a pinch, cow's milk would have to do.

Applicant's arguments filed 08 April 2003 have been fully considered but they are not persuasive. The rejections under 35 U.S.C. 102 are adhered to for the reasons of record and the additional reasons above.

Claim Rejections - 35 USC § 103

Claims 1-18, 35 and 38-39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Björck et al. (1979), Ho et al. (1978), Clark et al. (1976) and De Jong et al. (US 5,747,078) in view of Reddy et al. (US 5,876,990).

It is argued that none of the references suggest adding XOR to a human formula feed that is nutritionally complete. Reddy is said only to add XOR to animal feed to improve health and reduce odors. It is urged that there is no motivation to combine the references. It is urged that hindsight is used to combine the references.

The references are argued separately.

It is urged that Björck et al. (1979) only teach adding XOR substrates for antibacterial effect not XOR itself.

Motivation to combine Björck et al. (1979) with the other references is that Björck et al. (1979) establish that improved antibacterial effect in milk containing XOR is obtained by adding electron acceptor substrates (cf claims 8-9). It has been established above that the other primary references establish milk as suitable for human infant formula feed. It is not necessary to provide motivation to combine a given reference with every other relied upon reference.

It is argued that Ho et al. (1978) and Clark et al. (1976) do not teach an antibacterial effect. It is urged that De Jong et al. (US 5,747,078) is interested in long term preservation of foods.

Ho et al. (1978) and Clark et al. (1976) have been discussed previously. These references establish that XOR is in milk naturally, and even provide for greater than naturally occurring amounts of XOR in the animal feeds.

Motivation to combine comes from Reddy et al. (US 5,876,990) who establish the antibacterial effect of added XOR especially for the treatment of Scours. Given the teachings of Reddy et al. (US 5,876,990) a person of ordinary skill in the art would have recognized that the XOR in the formula feeds of Ho et al. (1978) and Clark et al. (1976) intrinsically contain enough XOR to provide for an antibacterial effect. The long term preservation of foods of De Jong et al. (US 5,747,078) is intrinsically an antibacterial effect, because the major impediment to long term preservation of foods is bacterial contamination and consequent degradation of the foods. Hence, at a minimum, De Jong et al. (US 5,747,078) also suggests the antibacterial effect of XOR (and other oxidoreductases).

Further, adding substrates to enhance the antibacterial effect is provided by Björck et al. (1979).

Applicant's arguments filed 08 April 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 103 is adhered to for the reasons of record and the additional reasons above.

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114.

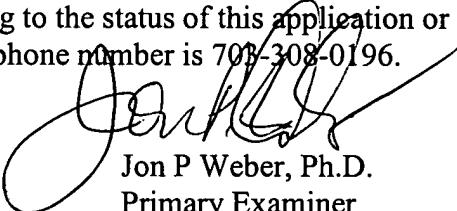
See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P. Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
June 12, 2003